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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,020	10/03/2005	Lawrence M Blatt	INTM-032/01US	2042

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
01/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,020	BLATT, LAWRENCE M	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed on Oct. 03, 2005 has been acknowledged. Claims 1, 8 and 12-13 have been amended. Claims 1-13 are pending and considered before the examiner.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Marco et al. (J. Viral Hepatology. Sept. 2002, Vol. 9(5), pp. 354-359), Okanoue et al. (J. Hepatology 1996, Vol. 25, pp. 283-291), Vial T. et al. (Chapter 13 in Biotechnology and Safety Assessment edited by Thomas et al. 1998, 2nd edition, pages 301-316) and Jaeckel et al. (N. Engl J. Med 2001, Vol. 345, pp. 1452-1457) and Keeffe et al. (Hepatology 1997, 26, Suppl. 1, pp. 121S-107S).

3. It is well known in that art that both INFα and INFγ has been widely used in the clinic for treating variety of viral infection, especially in combination with nucleoside for treatment of variety of viral infections, especially HCV and HBV infection as evidenced by Keeffe et al. and Jaecket et al. . They both teach how to use INF for treating for treating viral hepatitis infection, particularly, use s consensus INF. Di Marco et al. teach that a high dose of interferon treatment can get an early viral clearance and a sustained response in chronic HCV need to combine a lower dose of interferon with nucleoside analog such as ribavirin (See abstract).

4. However, INFs as a foreign protein, after it is injected into a patient usually, it usually causes varieties of side effects including flu like symptoms such as body pain, pyrexia, headache and fever as evidenced by Okanoue et al. (See abstract) and Vial T et al. (See pages 301-316). Vial et al. explicitly teach each of possible side effects and a method for treating or reducing the side effects with medications that are all categorized

as non-pirfenidone medicines according to the description by the current application (See specification on page 31).

5. Regarding the limitation of treatment within 24 to 48 or 35 days after exposure to the virus, Jaeckel et al. teach that treatment of acute hepatitis C infection with interferon should be started for the acute infection because the treatment of acute HCV infection can prevents chronic infection in the future (Abstract). The treatments start with subcutaneously administration of INFα-2b to patients in the acute infection or right after work-related accidents in Germany, including needle-stick injuries, even if they do not results in the transmission of any diseases (page 1453).

6. Therefore, in order to maintain the sustained effective treatment by INF treatment and control the side effect during the treatment, one of ordinary skill in the art would have been motivated by the cited references using a combining treatment plan comprising the INFs, nucleoside and other no-perifenidone medications together to increases the efficiency and sustained antiviral effects by INFs/ nucleoside and control the side effect in the patients as soon as the infection is identified. Hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Baoqun Li

Bao Qun Li
12/21/2007
7.

BAOQUN LI, MD
PATENT EXAMINER